COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Cetostearyl Alcohol BP (Item No. 41020680)	**Spec. No.** : SP-AK30-C41
Reference(s): BP 2020 page I-512 to I-513	**Rev. No.** : 04
Other Requirements: -	**Page** : 1/2

BP 2020

Test Parameters	Requirement	
Description	White or pale yellow, wax-like mass, plates, flakes or granules.	
Solubility	Practically insoluble in water, soluble in ethanol (96 per cent) and in light petroleum.	
Identification	Examine the chromatograms obtained in the assay. The 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time to the principal peaks in the chromatogram obtained with the reference solution.	
Appearance of solution	The solution is clear and not more intensely coloured than reference solution B_6.	
Melting point	49 °C – 56 °C.	
Acid value	Not more than 1.0.	
Hydroxyl value	208 – 228.	
Iodine value	Not more than 2.0.	
Saponification value	Not more than 2.0.	
Assay	Stearyl alcohol	: Not less than 40.0%.
	Sum of the contents of stearyl alcohol and cetyl alcohol	: Not less than 90.0%.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 02/09/20	Teerrin Lumbroom / 03/09/20	/ 08/09/20	Vichien Ruengpeerapej / 09/09/20	15/09/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Cetostearyl Alcohol (Item No. 41020680).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C41.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
03	Update ข้อกำหนดตาม BP 2013	19/09/14
04	Update ข้อกำหนดตาม BP 2020	15/09/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech / 02/09/20	Tawnie Lumlumsut / 03/09/20	/ 03/09/20	Vichien Ruengpongpoj / 09/09/20	15/09/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	